

BETADINE SURGICAL SCRUB- povidone-iodine solution

Avrio Health L.P.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Betadine Surgical Scrub

Drug Facts

Active ingredient

Povidone-iodine, 7.5% (0.75% available iodine)

Purpose

Antiseptic

Uses

- helps to reduce bacteria that potentially can cause skin infection
- for handwashing to reduce bacteria on the skin
- significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care

Warnings

For external use only

Do not use this product

- in the eyes

When using this product

- prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions

Stop use and ask a doctor

- if irritation and redness develop
- in rare instances of local irritation or sensitivity

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

A. **Surgical hand scrub:**

- wet hands with water

- spread about 5 cc (1 teaspoonful) of Scrub over both hands and forearms
- without adding more water, scrub thoroughly for 2 1/2 to 3 minutes
- use a sponge if desired. Clean thoroughly under fingernails.
- add a little water and develop copious suds. Rinse thoroughly under running water.
- repeat the entire procedure using another 5 cc of Scrub

B. Antiseptic hand wash:

- wet hands with water and pour about 5 cc of Scrub on hands
- rub hands vigorously together for at least 15 seconds, covering all surfaces
- rinse and dry with a disposable towel

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- store in original container

Inactive ingredients

ammonium nonoxynol-4 sulfate, nonoxynol-9, purified water, sodium hydroxide

Dist. by:

Avrio Health L.P. Stamford, CT 06901-3431

304954-0A

Betadine Surgical Scrub

NDC 67618-151-17

Not for Retail Sale

NDC 67818-151-17

For Professional and Hospital Use Only

BETADINE® Surgical Scrub

Povidone-iodine, 7.5%

Antiseptic Non-Sterile Scrub

Bactericidal/Virucidal Sudsing
Skin Cleanser

16 fl oz
(473 ml)



BETADINE SURGICAL SCRUB

povidone-iodine solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67618-151
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)		IODINE	.075 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
AMMONIUM NONOXYNOL-4 SULFATE (UNII: 9HIA70O4J0)				
NONOXYNOL-9 (UNII: 48Q180SH9T)				
WATER (UNII: 059QF0KO0R)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67618-151-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1996	
2	NDC:67618-151-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1996	
3	NDC:67618-151-17	1 in 1 CARTON	07/01/1996	
3		473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:67618-151-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1996	11/30/2024
5	NDC:67618-151-01	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/1996	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	07/01/1996	

Labeler - Avrio Health L.P. (141916531)

Registrant - Purdue Pharma LP (932323652)

Establishment

Name	Address	ID/FEI	Business Operations
Thatcher Company		041307356	MANUFACTURE(67618-151)

Revised: 12/2021

Avrio Health L.P.